

Replacement of antibiotic therapy by UroShield device in subjects with urinary catheter following radical prostatectomy

Introduction

Urinary tract infections (UTI) account for approx. 40% of all nosocomial infections. The urinary catheter is a primary source for such infections due to the colonization of bacteria on the catheter surface and the creation of biofilm. In addition since antibiotic treatment is less effective in treating biofilm, higher doses are needed thus increasing the risk of antibiotic resistant.

In this study, we have tested the potential of the UroShield ultrasound device in replacing antibiotic therapy in subjects requiring urinary catheter following radical prostatectomy.

Study design

This is a prospective, two arms randomized study.

Group 1 - Post operative single dose of Ceftriaxon 2g + Active UroShield

Group 2 - Post operative dose of Ceftriaxon 2g on Day 1-3 + trimetoprim 2x200mg per day until the end of the study.

Sample size

40 subjects were recruited for the study (20 subject in each group)

Study procedures

The overall plan for all subjects consists of the following elements:

1. Subjects were assessed for their eligibility to participate in the study according to the inclusions/exclusions criteria and signed a written informed consent according to Declaration of Helsinki and local regulations
2. Randomization procedure was performed in order to determined the subject's study group
3. Following the radical prostatectomy procedure, the UroShield was attached to the urinary catheter and activated (group 1 only)
4. Urine sample was taken for bacterial count (bacteriuria)
5. Catheter removal (based on PI decision)

6. Urine sample was taken for bacterial count (bacteriuria)
7. Study termination

Study objectives

This study is aimed to assess the safety and effectiveness of the UroShield device in replacing antibiotic therapy for preventing Bacteriuria/UTI in subjects following radical prostatectomy

Efficacy objectives

- Reduce bacteriuria/UTI following prostatectomy
- Reduce antibiotic usage

Results

The average age was 66.7 and 60.7 for group 1 and group 2, respectively. The average catheter days was 8.4 days (low - 7, high – 12) and 8.3 (low -7, high – 10) for group 1 and group 2, respectively

In group 1 there was one (1) case of bacteriuria at the end of the study (bacteriuria rate = 5%) while in group two 2 there were four (4) cases of bacteriuria at the end of the study (bacteriuria rate = 20%)

Conclusions

The results demonstrated that UroShield is **superior** to daily antibiotic treatment in preventing bacteriuria thus reducing UTI rate following radical prostatectomy. These results demonstrate a new approach to reducing antibiotic treatment, lessen the risk for bacterial resistance, and improve patient outcome by using UroShield ultrasound device.